

# **Exhibit 17**



UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934

For the Quarterly Period Ended September 30, 2001

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (d)  
OF THE SECURITIES EXCHANGE ACT OF 1934

For the Transition Period From \_\_\_\_\_ to \_\_\_\_\_

Commission File Number 1-9898  
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ORGANOGENESIS INC.

(Exact name of registrant as specified in its charter)

Delaware  
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(State or other jurisdiction of  
incorporation or organization)

150 Dan Road, Canton, MA  
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(Address of principal executive offices)

04-2871690  
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(I.R.S. Employer  
Identification number)

02021  
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(Zip Code)

Registrant's telephone number, including area code: (781) 575-0775  
\_\_\_\_\_

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes (X) No ( )

The number of shares outstanding of registrant's Common Stock, par value \$.01 per share, at November 2, 2001 was 37,065,120 shares (excluding treasury shares).



ORGANOGENESIS INC.

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In this report, "Organogenesis" "we" "us" and "our" refer to Organogenesis Inc.	



PART I - FINANCIAL INFORMATION  
Item 1 - Financial Statements

ORGANOGENESIS INC.  
CONSOLIDATED BALANCE SHEETS  
(In thousands, except share and per share data)

	December 31, 2000	September 30, 2001
	-----	-----
	(unaudited)	
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 9,539	\$ 2,483
Investments	2,644	-
Inventory	1,377	2,090
Receivable from related party	501	750
Other current assets	758	360
	-----	-----
Total current assets	14,819	5,683
Property and equipment -		
Less accumulated depreciation of \$13,600 and \$16,238	12,608	17,270
Other assets	445	369
	-----	-----
Total Assets	\$ 27,872	\$ 23,322
	=====	=====
<b>Liabilities</b>		
Current liabilities:		
Accounts payable	\$ 2,378	\$ 6,390
Accrued expenses	3,582	5,632
Current portion of term loan	1,576	-
Deferred revenue	1,057	1,057
	-----	-----
Total current liabilities	8,593	13,079
Deferred revenue	4,228	10,374
Long-term convertible debt	16,077	16,357
Term loan	2,758	-
Bank promissory note	-	5,000
Commitments (see notes)		
<b>Stockholders' Deficit</b>		
Common stock, par value \$.01; authorized 80,000,000 shares:		
Outstanding 34,489,459 and 35,294,626 shares as of		
December 31, 2000 and September 30, 2001, respectively	346	355
Additional paid-in capital	154,646	160,862
Accumulated deficit	(157,972)	(180,533)
Treasury stock, at cost, 85,000 shares at December 31, 2000		
and 250,000 shares at September 30, 2001	(804)	(2,172)
	-----	-----
Total stockholders' deficit	(3,784)	(21,488)
	-----	-----
Total Liabilities and Stockholders' Deficit	\$ 27,872	\$ 23,322
	=====	=====

The accompanying notes are an integral part of the consolidated financial statements.



## ORGANOGENESIS INC.

Consolidated Statements of Operations  
(Unaudited, in thousands, except share and per share data)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2000	2001	2000	2001
	(Restated Note 2)		(Restated Note 2)	
Revenues:				
Research, development and milestone support from related party	\$ 264	\$ 264	\$ 5,793	\$ 793
Product sales to related party	719	2,235	2,050	5,800
Research and development grants	258	227	732	740
Other revenues	78	225	198	258
Total Revenues	1,319	2,951	8,773	7,591
Costs and Expenses:				
Cost of product sales to related party	1,557	3,268	4,581	8,301
Research and development	4,417	4,110	12,827	13,062
Selling, general and administrative	1,770	2,445	5,624	7,323
Total Costs and Expenses	7,744	9,823	23,032	28,686
Loss from operations	(6,425)	(6,872)	(14,259)	(21,095)
Other income (expense):				
Interest income	341	6	917	129
Interest expense	(600)	(582)	(1,547)	(1,595)
Net loss before cumulative effect of change in accounting principle	(6,684)	(7,448)	(14,889)	(22,561)
Cumulative effect of adopting Staff Accounting Bulletin 101 ("SAB 101")	-	-	(6,342)	-
Net loss	\$ (6,684)	\$ (7,448)	\$ (21,231)	\$ (22,561)
Net loss per common share - basic and diluted before cumulative effect of change in accounting principle	\$ (0.19)	\$ (0.21)	\$ (0.45)	\$ (0.65)
Cumulative effect of adopting SAB 101	-	-	(0.19)	-
Net loss per common share - basic and diluted	\$ (0.19)	\$ (0.21)	\$ (0.64)	\$ (0.65)
Weighted average number of common shares outstanding - basic and diluted	34,315,711	34,962,994	33,216,444	34,634,246

The accompanying notes are an integral part of the consolidated financial statements.



## ORGANOGENESIS INC.

Consolidated Statements of Cash Flows  
(Unaudited, in thousands)

	For the Nine months Ended September 30,	
	2000	2001
	(Restated Note 2)	
Cash flows from operating activities:		
Net loss	\$(21,231)	\$(22,561)
Adjustments to reconcile net loss to cash flows used in operating activities:		
Depreciation	1,627	2,638
Issuance of stock options for services	-	171
Amortization of warrants and deferred debt issuance costs as interest expense relating to long-term convertible debt	379	356
Cumulative effect of adoption of SAB 101	6,342	-
Issuance of common stock for interest on convertible debt	696	619
Changes in assets and liabilities:		
Inventory	14	(713)
Other current assets and receivable from related party	218	149
Accounts payable	(732)	4,012
Accrued expenses and other current liabilities	(569)	2,050
Deferred revenue	(792)	6,146
Cash used in operating activities	(14,048)	(7,133)
Cash flows from investing activities:		
Capital expenditures	(2,082)	(978)
Capital expenditures reimbursed from related party	-	(6,322)
Sales and maturities of investments	3,357	2,644
Cash provided by (used in) investing activities	1,275	(4,656)
Cash flows from financing activities:		
Bank promissory note	-	5,000
Payment of term loan	-	(4,334)
Preferred stock redeemed in cash	(6,180)	-
Proceeds from sale of common stock - net	15,930	4,810
Proceeds from exercise of stock options	12,272	625
Purchase of treasury stock	-	(1,368)
Cash provided by financing activities	22,022	4,733
Increase (decrease) in cash and cash equivalents	9,249	(7,056)
Cash and cash equivalents, beginning of period	5,727	9,539
Cash and cash equivalents, end of period	\$ 14,976	\$ 2,483
	=====	=====

The accompanying notes are an integral part of the consolidated financial statements.



## ORGANOGENESIS INC.

Notes to Consolidated Financial Statements  
(Unaudited)1. BASIS OF PRESENTATION  
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The accompanying unaudited consolidated financial statements of Organogenesis Inc. have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, the accompanying consolidated financial statements include all adjustments, consisting of normal recurring adjustments, necessary for a fair presentation of the financial position, results of operations and changes in cash flows for the periods presented. The results of operations for the nine months ended September 30, 2001 are not necessarily indicative of the results to be expected for the year ending December 31, 2001.

These financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in our Form 10-K for the year ended December 31, 2000 as filed with the Securities and Exchange Commission.

Certain reclassifications have been made to the prior period financial statements to conform to the current presentation.

2. REVENUE RECOGNITION  
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We previously recognized up front non-refundable research and development support payments as revenue when received. During the year ended December 31, 2000, the Company changed its method of accounting for up front non-refundable research and development support payments to recognize such amounts over the term of the related collaboration with Novartis Pharma AG ("Novartis"). This change in accounting principle is in accordance with guidance provided in SEC Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements" (SAB 101), which was issued in December 1999 and summarizes certain of the Staff's views in applying generally accepted accounting principles to revenue recognition in financial statements. We adopted SAB 101 in the fourth quarter of 2000, retroactive to January 1, 2000, and recorded the cumulative effect of a change in accounting principle related to all up front non-refundable research and development support payments recognized in prior periods of \$6,342,000. Of this amount, \$793,000 was recognized as revenue during the nine months ended September 30, 2001 and 2000, respectively, and the remaining \$4,492,000 will be recognized ratably through December 2005, in accordance with SAB 101's guidance.

Revenues from non-refundable milestone payments are recognized when proceeds are received and the related costs and effort are considered substantive. No milestone revenues from the receipt of milestone payments were recorded during the nine months ended September 30, 2001.

Revenue from product sales are recognized upon shipment after risk of ownership passes to the buyer, collection is probable and we have no performance obligations. Product revenues which are performance based are deferred until performance is achieved. Revenues from product sales for the third quarter of 2001 totaled \$2,235,000. At September 30, 2001, we had \$149,000 of deferred performance based revenue.



Revenue from research grants is recognized to the extent of allowable costs incurred. We have recorded revenue of \$227,000 for the three months ended September 30, 2001 and \$740,000 for the nine months ended September 30, 2001 of which \$637,000 relates to a grant under the Advanced Technology Program of the National Institute for Standards and Technology (refer to footnote 8) and \$103,000 relates to other research grants.

Other revenues comprise funding received from Novartis for support activities related to the regulatory filing for Apligraf approval across the European Union and are recognized as costs are incurred. We received \$578,000, of which \$202,000 was recorded as other revenues for the three months ended September 30, 2001, related to this program. In addition, other revenues related to royalties are recorded as earned.

Revenue for funding received from Novartis for reimbursement of manufacturing facility expenditures will be recognized over the period that the completed manufacturing facility is used for production of Apligraf to be sold to Novartis. No revenues have been recognized to date. The funding was used to support facility investment needed for the approval and sale of Apligraf in the European Union and for upgrades to our manufacturing facility. During the nine months ended September 30, 2001, we received \$6,414,000 from Novartis for reimbursement of manufacturing facility costs of which \$6,322,000 was incurred during the nine months ended September 30, 2001 and \$485,000 was incurred in prior periods. Subsequent to September 30, 2001, we received reimbursement for all manufacturing facility costs incurred to date.

At September 30, 2001, long term deferred revenue of \$10,374,000 consisted of: funding received from Novartis for reimbursement of manufacturing facility costs of \$6,414,000; the unrecognized portion of funding received from Novartis for support activities related to the regulatory filing for Apligraf approval across the European Union of \$376,000; the unrecognized portion of product revenues received which are performance based of \$149,000; and the remaining deferred revenue related to adopting SAB 101 of \$3,435,000.

### 3. NET LOSS PER COMMON SHARE

Net loss per common share (basic and diluted) is based on the weighted average number of common shares outstanding during each period. Potentially dilutive securities at September 30, 2001 include: stock options outstanding to purchase 3,060,161 common shares; warrants to purchase 962,009 common shares; and debt convertible into 1,629,759 common shares; however, such securities have not been included in the net loss per common share calculation because their effect would be antidilutive. Potentially dilutive securities at September 30, 2000 included: stock options outstanding to purchase 3,931,400 common shares; warrants to purchase 900,000 common shares; and debt convertible into 1,736,813 common shares; however, such securities have not been included in the net loss per common share calculation because their effect would be antidilutive.

### 4. INVENTORY

Inventory is stated at the lower of cost or market, cost being standard cost, which approximates the first-in, first-out method of accounting. Inventory, at net realizable value, consisted of the following (in thousands):

	December 31, 2000	September 30, 2001
	-----	-----
	(unaudited)	
Raw materials	\$ 488	\$ 361
Work in process	889	1,729
	-----	-----
	\$1,377	\$2,090
	=====	=====



5. RELATED PARTY TRANSACTIONS  
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In January 1996, we entered into a collaborative agreement with Novartis granting Novartis exclusive global marketing rights to Apligraf. Under the agreement, we have received equity investments, non-refundable research, development and milestone support payments, product payments, funding for publication study programs and funding for European regulatory filing for Apligraf marketing approval. Product and other funding for programs are included under the captions "Product sales to related party" and "Other revenues" in our financial statements.

In February 2001, we amended our collaborative agreement with Novartis, effective January 2, 2001. The amended agreement:

- o Grants Novartis the right to purchase an exclusive option to negotiate terms to license Organogenesis's product Vitrix(TM) and also for a second living dermal replacement product currently in Organogenesis research;
- o Provides Organogenesis with significantly higher payments for units of Apligraf;
- o Grants Organogenesis the right for three years to sell, at its discretion, to Novartis up to \$20 million in equity or convertible debt;
- o Includes funding support from Novartis to upgrade Organogenesis's manufacturing facility and for the facility investment needed for approval and sale of Apligraf in the European Union;
- o Includes funding support for Apligraf clinical development activities (e.g., to further broaden its approved uses); and
- o Includes development funding support for each living dermal replacement product for which Novartis purchases an option to commence licensing negotiations.

We supply Novartis's global requirements for Apligraf and receive a product payment based on net product sales. Receivable from related party consists of amounts due on product sales to Novartis, funding of certain programs by Novartis and reimbursement of certain test costs related to the manufacturing of the product. Novartis is billed weekly for payments due on product sales and on an as incurred basis for other billings.

On June 29, 2001, we exercised a \$10,000,000 security option with Novartis, which closed on October 11, 2001. The security sold was a 7% Convertible Subordinated Note in the principal amount of \$10,000,000 with a maturity date of March 29, 2004. The note may be converted into shares of common stock at an adjusted conversion price of \$4.58 per share (subject to further adjustment) at any time by Novartis or by us at any time after March 31, 2002. Interest on the note accrues at 7% annually, payable in cash, common stock (at the average market price for the twenty trading days immediately proceeding the due date) or any combination thereof, at our option, on September 30 and March 31. Principal amounts due under the note, including accrued interest, may become immediately payable in cash if an event of default occurs, defined as: any default in the timely payment of principal, interest or liquidated expenses under the note; any representation or warranty made to Novartis which proves to have been incorrect when we made it under the note or the February 2001 Securities Purchase Agreement with Novartis or related documents; any failure to perform any covenant or agreement, or otherwise commit a breach under, the Note or the February 2001 Securities Purchase Agreement which is not remedied by us within 30 days of notice; any bankruptcy, insolvency or reorganization proceedings involving us or any of our subsidiaries; and the delisting or suspension of our common stock from trading on the AMEX without being relisted or having such suspension lifted within 30 trading days.



Additionally, if we fail to deliver to Novartis registered shares of our common stock on conversion of the Note, we will be required to pay to Novartis the greater of (a) actual expenses incurred by Novartis as a result of Novartis's need to purchase shares of common stock to satisfy its delivery requirements, and (b) on each date the conversion is not timely effected, an amount equal to one percent (1%) of the product of the number of shares of common stock not issued to Novartis on a timely basis and the closing bid price of our common stock on the last date that we could have issued shares of our common stock to Novartis without violating our delivery obligations.

As a result of previous equity investments made in prior years and not including conversion of the 7% Convertible Subordinated Note, Novartis holds approximately 1.9% of outstanding shares as of September 30, 2001. Assuming conversion of the 7% Convertible Subordinated Note, Novartis would hold approximately 7.2% of outstanding shares as of September 30, 2001.

During the third quarter of 2001, Novartis agreed to provide funding for support activities related to the regulatory filing for Apligraf marketing approval across the European Union. We received \$578,000, of which \$202,000 was recorded as other revenues for the three months ended September 30, 2001, related to this program. During the first quarter of 1999, Novartis agreed to provide funding for publication study programs to be conducted by us. We have recorded other revenues of \$11,000 and \$143,000 for the nine months ended September 30, 2001 and 2000, respectively, relating to the initiation of these programs.

#### 6. ACCRUED EXPENSES

Accrued expenses consisted of the following (in thousands):

	December 31, 2000	September 30, 2001
	-----	-----
	(unaudited)	
Compensation and employee benefits	\$1,869	\$2,117
Accrued Severance	-	988
Professional services	734	991
Accrued interest	368	654
Other	611	882
	-----	-----
	\$3,582	\$5,632
	=====	=====

#### 7. TERM LOAN AGREEMENT

In November of 1999, we entered into a \$5,000,000 term loan agreement with a commercial bank to finance the purchase of certain equipment, leasehold improvements and other items. Borrowings under the term loan were collateralized by a security interest in the items financed. The agreement provided for repayment of the principal amount of the loan in 12 equal quarterly installments commencing December 29, 2000, with final payment due on September 30, 2003. The loan bore interest at a fluctuating rate per annum that was equal to the prime rate in effect from time to time, or we could elect that all or any portion of any term loan be made as a LIBOR loan with an interest period of one month, two months, three months or six months with the interest rate being equal to LIBOR plus an applicable margin (175 to 225 basis points). We were required to comply with certain covenants relating to our outstanding term loans, involving limitations on future indebtedness, dividends and investments, and to maintain certain financial covenants pertaining to liquidity, capital base, and debt service coverage (or, alternatively, maintaining a minimum unencumbered cash balance). We borrowed approximately \$4,728,000 against this term loan to finance certain research, manufacturing and office equipment and leasehold improvements. The weighted average interest rate paid during this period was 7.82%. This borrowing was collateralized by a security interest in the fixed assets financed. On July 6, 2001, we paid \$3,562,000 which represented all outstanding principal and accrued interest under this term loan.



On June 29, 2001, we entered into a \$5,000,000 revolving credit agreement with a commercial bank and borrowed the full \$5,000,000 which was held in a cash collateral account pending payment in full of all obligations and release of all liens under the term loan. During July 2001, the full \$5,000,000 was released from the cash collateral account and \$3,562,000 was used to repay the term loan and the balance was used for general corporate purposes. On October 18, 2001, all outstanding amounts under this revolving credit agreement were paid in full. Subsequent loans may be made in an aggregate amount not to exceed the lesser of \$5,000,000 or 65% of our eligible receivable accounts. The revolving credit agreement provides for loans to be used for general business purposes with the interest rate being equal to the bank's prime rate plus two percent. Loans made under the revolving credit agreement are collateralized by a security interest in all of our assets and will become payable in a single installment on June 29, 2003.

#### 8. GRANT COMMITMENT

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In November 1999, we received notice of a \$2,000,000 grant under the Advanced Technology Program of the National Institute for Standards and Technology ("NIST") to help support development of an effective liver assist device prototype, of which we have received \$1,599,000 and expect to receive the remaining amount over the period through December 2001. This grant requires that the United States federal government can access for its own purpose technology developed using the funding. A product developed based on the funding from the NIST grant must be manufactured substantially in the United States. In addition, we are subject to regular audit and reporting requirements. We have recorded revenue of \$227,000 and \$637,000 for the three and nine months ended September 30, 2001, respectively, relating to this research grant.

#### 9. STOCKHOLDERS' EQUITY:

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##### COMMON STOCK

In April 2001, we issued 65,209 shares of common stock for payment of interest on our long-term convertible debt.

On May 4, 2001, the Securities and Exchange Commission declared effective an amendment to our shelf registration statement to sell to an underwriter up to a total of 1,900,000 shares of common stock from time to time during the two-year period ending April 2003. The number of shares sold may not be less than 5% and not more than 25% of the average trading volume of common stock on the American Stock Exchange for the previous five days. The purchase price of the shares we sell to the underwriter is the volume weighted average price for that trading day less an underwriting discount of 6% or 4.5%. In May and June 2001, we sold 237,200 shares of common stock to the underwriter yielding net proceeds of \$1,560,000 (after an underwriter's discount and offering expenses). On October 11, 2001, we placed 1,670,645 shares of common stock under the shelf registration, yielding gross proceeds of \$7,000,000, to a group of predominately new investors.

During the nine months ended September 30, 2001, we issued 163,882 shares of common stock for the exercise of employee stock options, yielding proceeds of approximately \$625,000.

On August 28, 2001, two directors and one additional investor purchased 503,876 shares of common stock, yielding proceeds of \$3,250,000. In addition, the investors received three-year warrants to purchase an aggregate of 62,009 shares of common stock at \$8.55 per share.



#### OPTIONS ISSUED TO A CONSULTANT

In May 2001, we executed an agreement granting options to purchase 35,000 shares of common stock at an exercise price of \$8.10 per share to a consultant. These options were issued fully vested and exercisable, with an expiration of five years. During the nine months ended September 30, 2001, we recorded an expense of \$171,000 relating to the fair value of these options (using an option-pricing model).

#### 10. TREASURY STOCK:

In December 2000, the Board of Directors authorized a common stock repurchase program for up to 500,000 shares. Repurchases are allowed through open-market transactions that will provide us with shares for general corporate purposes. In January 2001, we repurchased 165,000 shares of common stock for an aggregate purchase price of approximately \$1,368,000. The stock repurchase program may be discontinued at any time.

We had in treasury 85,000 shares of common stock at a cost of \$804,000 and 250,000 shares of common stock at a cost of \$2,172,000, at December 31, 2000 and September 30, 2001, respectively.

#### 11. SEVERANCE AGREEMENT:

In May 2001, we entered into a separation of employment agreement with a former executive officer, which resulted in the recording of a one-time severance expense of \$1,233,000 during the quarter ended June 30, 2001. The separation of employment agreement provides for amounts to be paid over two years and supercedes the previous employment agreement.

#### 12. NEW ACCOUNTING PRONOUNCEMENTS:

In July 2001, the Financial Accounting Standards Board issued SFAS No. 141, "Business Combinations" and SFAS No. 142, "Goodwill and Other Intangible Assets." SFAS No. 141 requires that all business combinations be accounted for under the purchase method only and that certain acquired intangible assets in a business combination be recognized as assets apart from goodwill. SFAS No. 142 requires that ratable amortization of goodwill be replaced with periodic tests of the goodwill's impairment and that intangible assets other than goodwill be amortized over their useful lives. SFAS No. 141 is effective for all business combinations initiated after June 30, 2001 and for all business combinations accounted for by the purchase method for which the date of acquisition is after June 30, 2001. The provisions of SFAS No. 142 will be effective for fiscal years beginning after December 15, 2001, and will thus be adopted by us, as required, in fiscal year 2002. We do not expect that the application of SFAS No. 141 and SFAS No. 142 will have a material impact on our financial position or results of operations.

In October 2001, the Financial Accounting Standards Board issued SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets." SFAS 144 supercedes FASB Statement No. 121 (SFAS 121), "Accounting for the Impairment of Long-Lived Assets and for Long Lived Assets to Be Disposed of." SFAS 144 applies to all long-lived assets (including discontinued operations) and consequently amends Accounting Principles Board Opinion No. 30 (APB 30), "Reporting Results of Operations - Reporting the Effects of Disposal of a Segment of a Business." SFAS 144 is effective for financial statements issued for fiscal years beginning after December 15, 2001, and will thus be adopted by the Company, as required, on January 1, 2002. Management is currently determining what effect, if any, SFAS 144 will have on its financial position and results of operations.

#### 13. SUBSEQUENT FINANCING ACTIVITIES:

On October 11, 2001, we received proceeds of \$10,000,000 from the sale of a 7% Convertible Subordinated Note to Novartis with a maturity date of March 29, 2004. Also on October 11, 2001, we placed the remaining 1,670,645 shares of common stock under the shelf registration, yielding proceeds of \$7,000,000. On October 18, 2001, all outstanding amounts under the revolving credit agreement were paid in full. (Refer to footnotes 5, 7 and 9 for a full description).



## ORGANOGENESIS INC.

## Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

This Form 10-Q contains forward-looking statements that involve risks and uncertainties. Forward-looking statements include information on:

- o Our business outlook and future financial performance;
- o Anticipated profitability, revenues, expenses and capital expenditures;
- o Anticipated research, development, clinical, regulatory and reimbursement progress;
- o Future funding and expectations as to any future events; and
- o Other statements that are not historical fact and are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve risks and uncertainties.

Although we believe that our plans, intentions and expectations reflected in or suggested by such forward-looking statements are reasonable, we can give no assurance that such plans, intentions or expectations will be achieved. When considering such forward-looking statements, you should keep in mind the risk factors and other cautionary statements in this Form 10-Q and in other publicly available filings with the US Securities and Exchange Commission ("SEC"), such as our Annual Report on Form 10-K for the year ended December 31, 2000 and our recent Registration Statement on Form S-3 filed on November 1, 2001. The risk and other factors noted throughout this Form 10-Q could cause our actual results to differ materially from the results contained in any forward-looking statements.

In Management's Discussion and Analysis ("MD&A"), we explain the general financial condition and results of operations for Organogenesis Inc. As you read this MD&A, referring to our consolidated financial statements contained in Item 1 of this Form 10-Q may be helpful. Results of operations may vary significantly from quarter to quarter depending on, among other factors: the progress of our research and development efforts; the receipt of research, development and other support payments, if any, from Novartis; product revenues; manufacturing, sales and marketing costs; the timing of certain expenses and the establishment of additional collaborative agreements, if any.

## OVERVIEW OF ORGANOGENESIS Inc.

Organogenesis Inc. designs, develops and manufactures medical products containing living cells and/or natural connective tissue. We are the first tissue engineering company to develop, manufacture and gain US Food and Drug Administration ("FDA") approval for a mass-produced product containing living human cells that targets large markets. Our product and research portfolio includes living tissue replacements, bio-engineered collagen matrix products, a cell-based organ assist device and other tissue-engineered products.

## APLIGRAF(R) SKIN SUBSTITUTE

Our lead product, Apligraf skin substitute, is FDA approved and marketed in the US for two uses: treatment of healing-resistant venous leg ulcers, approved May 1998, and treatment of healing-resistant diabetic foot ulcers, approved June 2000. Novartis Pharma AG ("Novartis") has exclusive global Apligraf marketing rights. In recent months, decisions made at the national and regional level have expanded access to Apligraf by Medicare-insured patients, and the product is now being reimbursed by Medicare in all fifty states. Apligraf is also available in select international markets. In April 2001, Novartis submitted the regulatory filing for marketing approval across the European Union.

Apligraf(R) is a registered trademark of Novartis.



A pivotal trial is underway to assess the ability of Apligraf to reduce scarring after skin cancer surgery. We expect to complete this trial and submit to the FDA for marketing approval in 2002. As a skin substitute, we believe Apligraf has a number of additional potential uses, including treating pressure ulcers, burns, epidermolysis bullosa (a genetic skin disorder) and other chronic and acute wounds.

#### FORTAFLEX(TM) -BASED PRODUCTS

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We are leveraging our FortaFlex(TM) bioengineered collagen matrix technology into a family of products. In October 2001, we launched FortaPerm(TM) bioengineered tissue support product. FortaPerm is being marketed by our own sales and marketing team. We also expect commercialization of our FortaGen(TM) bioengineered tissue repair product to begin in the first quarter 2002 and of our PuraPly(TM) wound dressing to begin in the fourth quarter 2001. Royce(R) Medical Company has marketing rights for the US non-hospital market for PuraPly. We also have recently entered into a collaboration agreement with Biomet, Inc. which grants Biomet the right to develop and market FortaFlex-based orthopedic and periodontal products in exchange for royalties.

#### OUR PIPELINE

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We are developing a cosmetic product, Revitix(TM) Regenerative Skin Complex, for use following laser resurfacing and chemical peel procedures, which is expected to begin commercialization in 2002. Our research and development pipeline also includes a living dermal replacement product candidate, Vitrix(TM). We have initiated a clinical study for Vitrix in the treatment of deep diabetic foot ulcers. Our pipeline also includes a coronary vascular graft and a liver assist device, both currently in animal studies.

#### RESULTS OF OPERATIONS

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We are currently at low volume production for Apligraf. Although revenues are ramping-up, as evidenced by the unit growth in each quarter, we expect production costs to exceed product sales for at least the next six months due to the high costs associated with low unit volume production. We expect production volume to increase due to recently expanded Medicare coverage for Apligraf, FDA approval of Apligraf for use in diabetic foot ulcers and expanded Novartis sales and marketing support.

#### REVENUES

Product revenues for the quarter ended September 30, 2001 increased 211% to \$2,235,000, from \$719,000 for the comparable quarter last year. Product revenues for the nine-month period ended September 30, 2001 increased 183% to \$5,800,000, from \$2,050,000 for the comparable period last year. These increases were due to significantly higher payments received for units of Apligraf sold to Novartis under the amended collaborative agreement that became effective January 2, 2001 and to increased unit sales of Apligraf to Novartis. Product revenues increased even though commercial sales were suspended for a time following the September 11, 2001 terrorist attack. We expect Apligraf commercial sales to continue to increase. Research, development and milestone support from related party for the nine months ended September 30, 2000 includes a \$5,000,000 payment from Novartis for achievement of a milestone related to the diabetic foot ulcer indication. No such payments have been received in 2001.

Royce(R) is a registered trademark of Royce Medical Company.



## COSTS AND EXPENSES

Cost of product sales: Cost of product sales for the quarter ended September 30, 2001 increased 110% to \$3,268,000, from \$1,557,000 for the comparable quarter last year. Cost of product sales for the nine-month period ended September 30, 2001 increased 81% to \$8,301,000, from \$4,581,000 for the comparable period last year. These increases were due to increased unit sales of Apligraf to Novartis, higher allocation of depreciation and occupancy costs, and increased scrap charges during the month of September due to the suspension of commercial sales of Apligraf following the September 11, 2001 terrorist attack. Cost of product sales includes the direct costs to manufacture, quality inspect and package Apligraf and an allocation of our production-related indirect costs. Cost of product sales continues to exceed product sales due to the high costs associated with low volume production. We expect production volume to increase and our margins to continue to improve during the remainder of 2001. We expect that we will have to revise standard costs and the allocation of costs to product sales in the future as we continue to modify our manufacturing processes.

Research and development: Research and development expenses ("R&D") consist of costs associated with research, development, clinical, process development, facilities and engineering support excluding the allocation of our production related indirect costs. R&D expenses for the quarter ended September 30, 2001 decreased 7% to \$4,110,000, from \$4,417,000 for the comparable quarter last year. R&D expenses for the nine-month period ended September 30, 2001 increased 2% to \$13,062,000, from \$12,827,000 for the comparable period last year, due to: increased clinical outside service and consulting costs related to further broadening Apligraf uses; increased process development costs related to manufacturing improvement programs and increased product development costs related to our Technology Ventures business unit. We expect that R&D expenses will continue to increase moderately during the remainder of 2001.

Selling, general and administrative expenses: Selling, general and administrative expenses ("SG&A") include the costs of our corporate, finance, information technology, human resource and Technology Ventures business unit functions. SG&A expenses for the quarter ended September 30, 2001, increased 38% to \$2,445,000, from \$1,770,000 for the comparable quarter last year. SG&A expenses for the nine-month period ended September 30, 2001, excluding a one-time severance expense of \$1,233,000, increased 8% to \$6,090,000 from \$5,624,000 for the comparable period last year. Both period increases were due mainly to higher costs related to recording the fair value of stock options issued for consulting services, higher professional service expenses and new selling expenses related to commercial product launch. We expect that SG&A expenses will increase during the remainder of 2001 as we continue to incur new selling expenses related to our Technology Ventures business unit function. Severance expense for the nine month period ended September 30, 2001 represents a one-time expense of \$1,233,000 related to the separation of employment of a former executive officer. No severance expense was recorded for the comparable period last year.

Other income and expense: Interest income for the quarter ended September 30, 2001 decreased 98% to \$6,000, from \$341,000 for the comparable quarter last year. Interest income for the nine-month period ended September 30, 2001 decreased 86% to \$129,000 from \$917,000 for the comparable period last year. These decreases were primarily due to the decrease in funds available for investment. Interest expense for the quarter ended September 30, 2001 decreased 3% to \$582,000, from \$600,000 for the comparable quarter last year. Interest expense for the nine-month period ended September 30, 2001 increased 3% to \$1,595,000 from \$1,547,000 for the comparable period last year.



## NET LOSS

As a result of the net effects described above, our net loss for the quarter ended September 30, 2001 was \$7,448,000 or \$0.21 per share (basic and diluted), compared to \$6,684,000, or \$0.19 per share (basic and diluted), for the comparable quarter last year. Our net loss for the nine-month period ended September 30, 2001 was \$22,561,000 or \$0.65 per share (basic and diluted), compared to \$14,889,000, or \$0.45 per share (basic and diluted), before the cumulative effect of change in accounting principle, for the comparable period last year, and a net loss effected for the change in accounting principle of \$21,231,000, or \$0.64 per share (basic and diluted), for the comparable period last year.

## CAPITAL RESOURCES AND LIQUIDITY

## FUNDS USED IN OPERATIONS

At September 30, 2001, we had cash, cash equivalents and investments in the aggregate amount of \$2,483,000, compared to \$12,183,000 at December 31, 2000. Cash equivalents consist of money market funds, which are highly liquid and have original maturities of less than three months. Investments consist of securities that have an A or A1 rating or better with a maximum maturity of two years. Cash used in operating activities for the nine months ended September 30, 2001 was \$7,133,000, primarily for funding our net loss, offset by \$6,414,000 cash received from Novartis related primarily for funding the investment needed for approval and sale of Apligraf in the European Union. Cash used in operating activities for the nine months ended September 30, 2000 was \$14,048,000, primarily for funding our net loss, offset by \$5,000,000 in cash received from Novartis for achievement of a milestone related to the diabetic foot ulcer indication.

## CAPITAL SPENDING

Capital expenditures were \$7,300,000 (of which \$6,322,000 was incurred for facility upgrades which is being funded by Novartis) and \$2,082,000 during the nine months ended September 30, 2001 and 2000, respectively, primarily related to the further build-out of existing facilities to support Apligraf manufacturing. We will continue to utilize funds during the remainder 2001 to expand our existing facility in the areas of Apligraf manufacturing, packaging and other process development improvement programs, including funds which we will receive from Novartis to upgrade our manufacturing facility and for the facility investment needed for approval and sale of Apligraf in the European Union.

## NOVARTIS SUPPORT

During the nine months ended September 30, 2001, Novartis provided funding support of \$6,414,000 for upgrades to our manufacturing facility and for the facility investment needed for approval and sale of Apligraf in the European Union. We have recorded the full amount of this funding as deferred revenue for the period ended September 30, 2001. Revenue will be recognized over the period that the completed manufacturing facility is used for production of Apligraf to be sold to Novartis, which is expected to start in 2002. We have incurred \$6,322,000 during the nine months ended September 30, 2001 and \$485,000 was incurred in prior periods. Subsequent to September 30, 2001, we received reimbursement for all manufacturing facility costs incurred to date.

During the third quarter of 2001, Novartis agreed to provide funding for support activities related to the regulatory filing for Apligraf marketing approval across the European Union. We received \$578,000, of which \$202,000 was recorded as other revenues for the three months ended September 30, 2001, related to this program. During the first quarter of 1999, Novartis agreed to provide funding for publication study programs to be conducted by us. We have recorded other revenues of \$11,000 and \$143,000 for the nine months ended September 30, 2001 and 2000, respectively, relating to the initiation of these programs.



## FINANCING

From inception, we have financed our operations substantially through public offerings and private placements of equity securities, as well as receipt of research support and contract revenues, interest income from investments, sale of products and receipt of royalties. During the nine months ended September 30, 2001, financing activities provided cash of \$4,733,000 primarily due to: proceeds received from a bank promissory note for \$5,000,000; cash received from the exercise of stock options for \$625,000; and the sale of common stock that generated net proceeds of \$4,810,000 offset by the purchase of treasury stock totaling \$1,368,000 and payment of a term loan for \$4,334,000. Financing activities provided cash of \$22,022,000 for the nine months ended September 30, 2000 primarily from the sale of common stock that generated net proceeds of \$15,930,000 and the exercise of stock options that generated \$12,272,000, partially offset by the redemption of Series C redeemable convertible preferred stock in cash for \$6,180,000.

We have received \$20,250,000 from recent financing activities as follows:

- o On August 28, 2001, two directors and one additional investor purchased 503,876 shares of common stock yielding proceeds of \$3,250,000.
- o On October 11, 2001, we received proceeds of \$10,000,000 from the sale of a 7% Convertible Subordinated Note to Novartis with a maturity date of March 29, 2004.
- o On October 11, 2001, we placed to a group of predominately new investors the remaining 1,670,645 shares of common stock under the shelf registration, yielding proceeds of \$7,000,000.

## LIQUIDITY

We have incurred a net loss for the quarter and nine months ended September 30, 2001 and have negative stockholders' equity at September 30, 2001. On a pro-forma basis, giving consideration to the cash received subsequent to September 30, 2001, we have working capital of \$9,604,000. We have not achieved profitability and expect to continue to incur net losses through at least the third quarter of 2002. We will need to raise additional funds to support our operations.

Based upon our current plans, we believe that the \$17,000,000 received subsequent to September 30, 2001, together with product and other revenues, and proceeds available from the remaining \$10,000,000 security option with Novartis, which is at our discretion, will be sufficient to finance operations through the first quarter of 2002. We expect to raise additional funds through equity financing. However, this statement is forward-looking and changes may occur that would significantly decrease available cash before such time. Factors that may change our cash requirements include:

- o Sales volume forecasts not achieved;
- o Delays in obtaining regulatory approvals of products in different countries, if needed, and subsequent timing of product launches;
- o Delays in commercial acceptance and reimbursement when product launches occur;
- o Changes in the progress of research and development programs;
- o Changes in the resources devoted to outside research collaborations or projects, self-funded projects, proprietary manufacturing methods and advanced technologies.
- o Potential repayment of the principal amount of the 7% Convertible Subordinated Promissory Note that we issued to Novartis as of September 28, 2001, together with all accrued but unpaid interest on the Note and other amounts that we owe to Novartis on the date of acceleration of the Note, that would be required if we defaulted on our obligations under the Note; and
- o Payments to Novartis under the Note if we fail to deliver to Novartis registered shares of our common stock upon Novartis' conversion of the Note.



Any of these events could adversely impact our capital resources, requiring us to raise additional funds. Management believes that additional funds may be available through equity or debt financing, strategic alliances with corporate partners, capital lease arrangements, or other sources of financing in the future. For the long-term, we expect to be generating cash from operations and to a lesser extent, raising funds from additional equity financing. There can be no assurance that these funds will be available when required on terms acceptable to us, if at all. If adequate funds are not available when needed, we would need to delay, scale back or eliminate certain research and development programs or license to third parties certain products or technologies that we would otherwise undertake ourselves, resulting in a potential adverse effect on our financial condition and results of operations.

#### NEW ACCOUNTING PRONOUNCEMENT:

In October 2001, the Financial Accounting Standards Board issued SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets." SFAS 144 supercedes FASB Statement No. 121 (SFAS 121), "Accounting for the Impairment of Long-Lived Assets and for Long Lived Assets to Be Disposed of." SFAS 144 applies to all long-lived assets (including discontinued operations) and consequently amends Accounting Principles Board Opinion No. 30 (APB 30), "Reporting Results of Operations - Reporting the Effects of Disposal of a Segment of a Business." SFAS 144 is effective for financial statements issued for fiscal years beginning after December 15, 2001, and will thus be adopted by the Company, as required, on January 1, 2002. Management is currently determining what effect, if any, SFAS 144 will have on its financial position and results of operations.

#### ADDITIONAL CAUTIONARY CONSIDERATIONS

We are subject to risks, including, but not limited to, the following uncertainties:

- o Continued operating losses and the time required to achieve profitability;
- o Market acceptance of our products and successful marketing and selling of Apligraf by Novartis;
- o Availability of additional capital by the first quarter of 2002 on acceptable terms, if at all;
- o Development by competitors of new technologies or products that are more effective than ours;
- o Dependence on our strategic relationships to market our products;
- o Compliance with FDA regulations and similar foreign regulatory bodies;
- o Protection of proprietary technology through patents and risks of infringement claims by third parties;
- o Manufacture and sale of products in sufficient volume to realize a satisfactory margin;
- o Continued availability of raw material for products;
- o Product quality issues which could lead to product recalls;
- o Dependence on and retention of key personnel;
- o Availability of sufficient product liability insurance;
- o Adequate third-party reimbursement for products;
- o Stock price volatility and fluctuation;
- o Affect of anti-takeover measures on the value of our stock;
- o Affect of outstanding options, warrants and convertible debt on the value of our stock;
- o Risk of failure of clinical trials for future indications of Apligraf and for Vitrix and other products;
- o Terrorist activities or the concerns regarding potential terrorist activities may make it impossible to ship our products; and
- o We may not be successful in marketing our own products, which we have just begun to commercialize.

#### ITEM 3 QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The exposure of market risk associated with risk-sensitive instruments is not material, as our sales are transacted primarily in United States dollars, we invest primarily in money market funds and we have not entered into hedging transactions.



## ORGANOGENESIS INC.

## PART II - OTHER INFORMATION

## ITEM 2. CHANGES IN SECURITIES AND USE OF PROCEEDS.

On September 5, 2001, we entered into a term sheet with two of our directors and one additional investor (collectively, the "Purchasers"). Pursuant to the term sheet, we issued and sold to the Purchasers an aggregate of 503,876 shares of our common stock and warrants to purchase 62,009 shares of our common stock for an aggregate purchase price of \$3,250,000. No underwriters were involved and no underwriting discounts or commissions were paid in connection with the offering. Such offering was exempt from registration under the Securities Act of 1933, as amended (the "Securities Act") pursuant to Rule 506 of Regulation D thereof because there were no more than 35 purchasers and the terms and conditions of Rule 501 and Rule 502 of Regulation D were satisfied. The warrants are exercisable for a period of three years at a purchase price of \$8.55 per share. In connection with the offering, we entered into a Registration Rights Agreement, dated as of August 28, 2001, with the Purchasers. Pursuant to the Registration Rights Agreement, we filed a registration statement with the Securities and Exchange Commission (the "Commission") on November 1, 2001 covering the resale by the Purchasers of the shares of our common stock sold directly to the Purchasers and the shares of our common stock issuable to the Purchasers upon the exercise of the warrants.

## ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

## (a) Exhibits

- 10.1 Form of Common Stock Purchase Warrant dated as of August 28, 2001 (Filed as Exhibit 10.3 to the Registrant's Registration Statement on Form S-3 filed with the Securities and Exchange Commission on November 1, 2001 and incorporated herein by reference).
- 10.2 Registration Rights Agreement, dated as of August 28, 2001, by and among the Registrant, Alan Ades, Glenn Nussdorf and Bernard Marden (Filed as Exhibit 10.4 to the Registrant's Registration Statement on Form S-3 filed with the Securities and Exchange Commission on November 1, 2001 and incorporated herein by reference).

- (b) No current reports on Form 8-K were filed during the quarter ended September 30, 2001.



ORGANOGENESIS INC.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ORGANOGENESIS INC.  
(Registrant)

Date: November 14, 2001

/S/ Michael L. Sabolinski

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Michael L. Sabolinski, M.D., President  
and Chief Executive Officer  
(Principal Executive Officer)

Date: November 14, 2001

/S/ John J. Arcari

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John J. Arcari, Vice President, Finance and  
Administration, Chief Financial Officer  
(Principal Financial and Accounting Officer)



